

Action as it Relates to the Living Substance"; "Einstein's Law of Photo Electric Effect"; and "Blood Test."

RESULTS OF INVESTIGATION: Examination with the use of a beta-gamma survey meter disclosed that the center of the assembled devices possessed radioactivity in the amount of 17 milliroentgens per hour which is about 2 to 3 times that of a radium dial watch.

LIBELED: 1-11-60, Dist. Ariz.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the article contained false and misleading representations that the device was an adequate and effective treatment for arthritis, diabetes, anemia, cancer, numerous bone ailments, to dissolve blood clots and eliminate inflammation through irradiation of a series of samples of a person's blood and the re-injection of the blood plasma after irradiation; 502(b) (1)—the device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(f) (1)—the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, the prevention and treatment of epilepsy, leukemia, cancer, arthritis, and mentally retarded children, which were the conditions and diseases for which the device was recommended orally by A. F. Mercier.

DISPOSITION: On 2-24-60, A. F. Mercier appeared as claimant and filed a motion to dismiss, which was denied by the court on 3-15-60. On 3-21-60, the claimant filed a claim and answer denying that the article was misbranded. Thereafter, the Government filed interrogatories against the claimant which were answered in part after which the Government filed supplemental interrogatories. On 4-13-60, the Government filed a motion for summary judgment on the ground that there was no genuine issue as to any material fact with respect to the charges of misbranding under 502(b) (1) and 502 (f) (1). The motion was granted on 5-6-60, and, on 7-1-60, the articles were ordered condemned and delivered to the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS FOR HUMAN USE

6209. Thyroid-digitalis tablets and thyroid tablets. (F.D.C. No. 43708. S. Nos. 23-389/90 P.)

INFORMATION FILED: 4-11-60, S. Dist. Calif., against Joseph L. Jones, t/a J. L. Jones & Co., Sun Valley, Calif.

SHIPPED: 9-18-58 and 10-16-58, from California to Nevada.

LABEL IN PART: (Ctn.) "J. L. JONES & COMPANY Manufacturing Chemists 7200 Vineland Ave., Sun Valley, California MANUFACTURED FOR * * * Each tablet contains: Thyroid U.S.P. 3 grains Digitalis Leaves Powder $\frac{3}{4}$ grain Plus added excipients 10 = 71 grains * * * IMPORTANT This is a bulk shipment, intended for further processing only." or "J. L. JONES & COMPANY Manufacturing Chemists * * * Each tablet contains: Thyroid 5 grains Plus added excipients 10 = 165 grains * * * S. C. Blue."

RESULTS OF INVESTIGATION: The *thyroid-digitalis tablets* contained about 76 percent of the labeled amount of thyroid and 58 percent of the labeled amount of digitalis per tablet, and the *thyroid tablets* contained about 65 percent of the labeled amount of thyroid per tablet.

CHARGE: 501(c)—the strength of the *thyroid-digitalis tablets* differed from that which they were represented to possess; and 502(a)—the statement "Each tablet contains: Thyroid 5 grains" on the label of the *thyroid tablets* was false and misleading.

The information alleged also that a number of food supplement tablets were adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

PLEA: Nolo contendere.

DISPOSITION: 6-13-60. \$750 fine.

6210. Syngesterone (progesterone). (F.D.C. No. 44562. S. Nos. 98-803 P, 996 R, 1-662 R.)

QUANTITY: 350 individually cartoned 10-cc. vials at Chamblee, Ga.

SHIPPED: 12-14-59, from Brooklyn, N.Y., by Chas. Pfizer & Co., Inc.

LABEL IN PART: (Ctn. and vial) "Syngesterone Brand of Progesterone, U.S.P. in aqueous suspension 25 mg./cc. For Intramuscular Use Only * * * Chas. Pfizer & Co., Inc., New York, New York."

ACCOMPANYING LABELING: Leaflet in carton entitled "Syngesterone Brand of Progesterone U.S.P."

RESULTS OF INVESTIGATION: Examination showed that the article contained from 69.7 percent to 124.1 percent of the labeled amount of *progesterone*. The United States Pharmacopeia requires that sterile progesterone suspension contain not less than 93 percent and not more than 107 percent of the labeled amount of *progesterone*.

LIBELED: 5-4-60, N. Dist. Ga.

CHARGE: 501(b)—when shipped, the strength of the article differed from and its quality fell below the standard for "Sterile Progesterone Suspension" set forth in the United States Pharmacopeia; and 502(a)—the name "Syngesterone Brand of Progesterone, U.S.P. in Aqueous Suspension 25 mg./cc." was false and misleading.

DISPOSITION: 6-14-60. Default—destruction.

6211. Vitamin B₁₂ injection. (F.D.C. No. 44452. S. No. 27-713 R.)

QUANTITY: 6 10-cc. vials at Davenport, Iowa.

SHIPPED: 3-22-60, from Minneapolis, Minn.

LIBELED: 5-11-60, S. Dist. Iowa.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "Each cc. contains: Vitamin B₁₂ activity * * * equivalent to: Cyanocobalamin 10 Mcg * * * Fortified with vit. B₁₂ cryst 100 mcg" was false and misleading as applied to the article which contained less than 50 percent of the declared amount of vitamin B₁₂.

DISPOSITION: 5-27-60. Consent—destruction.

DRUG FOR VETERINARY USE

6212. Egg ration. (F.D.C. No. 44575. S. Nos. 7-045/6 R.)

QUANTITY: 22 100-lb. bags and 6 100-lb. bags at Fairfield, Vt.

SHIPPED: Some time within the 6 months period prior to 5-6-60, from Oneonta, N.Y., by Elmore Milling Co., Inc.